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MAY 31 2002

ATTACHMENT 3
Revised 510(K) SUMMARY

Submitter: Molecular Diagnostics, Inc.

Contact Person:
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414 North Orleans, Suite 510
Chicago, IL 60610
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Date Prepared: May 28, 2002

Trade Name: InPath™ e^2 Collector™

Classification Name: and Number: Class II, 21 CFR 884.4530

Product Code: HHT

Predicate Device(s): The Molecular Diagnostics, Inc. InPath™ e^2 Collector™ cervical cytology collection device is substantially equivalent to the Digene Cervical Brush from the Digene Corporation (K971586) and the Rovers Cervex-Brush (K930955).

Device Description: The InPath e^2 Collector (e^2 Collector) is a multi-component assembly for the collection and transport of exfoliated cervical epithelial cells. The major e^2 Collector components are a balloon that provides the conformal surface upon which the cells are collected, and a handle that provides a means of manipulating and expanding the balloon during the sampling process.

The balloon consists of a medical grade silicone and colorant. The tip of the balloon is designed to be expanded during sampling by at least a factor of two over its resting diameter to accommodate the range of endocervical canal diameters commonly encountered in clinical practice. The body of the balloon is sized to collect cells from an area of the ectocervix, centered on the cervical canal, which is approximately 23 mm-diameter. The balloon tip measures about 3 mm in diameter, and 12 mm in length when un-inflated, and it can be introduced without difficulty to the endocervix.

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Intended Use:

The InPath™ e^2 Collector™ is intended for the collection of cervical cytology specimens for Pap test analysis. The InPath™ e^2 Collector™ should not be used after the first 10 weeks of gestation in pregnant patients.

Functional and Safety Testing:

Representative samples of InPath™ e^2 Collectors underwent design testing to demonstrate substantially equivalent functional characteristics. In addition, manufacturing process testing is done to assure that the devices produced meet design requirements.

Conclusion:

The InPath™ e^2 Collector™ manufactured by Molecular Diagnostics, Inc. is substantially equivalent to the Digene Cervical Brush from the Digene Corporation (K971586) and the Rovers Cervex-Brush (K930955). This conclusion is based upon the fact that these devices have essentially identical indications for use, substantially equivalent principles of operation, and clinical trial results that demonstrate performance equal to, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

Molecular Diagnostics, Inc.
% Ms. Ann Quinlan-Smith
Consultant to Molecular Diagnostics
Alquest, Incorporated
4050 Olson Memorial Hway., Suite 350
MINNEAPOLIS MN 55422

Re: K013258
Trade/Device Name: InPath™ e² Collector
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: 85 HHT
Dated: March 29, 2002
Received: March 29, 2002

Dear Ms. Quinlan-Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Page

510(k) Number (if known): K013258

Device Name: The InPath™ e^2 Collector™

Indications for Use:

The InPath™ e^2 Collector™ is intended for the collection of cervical cytology specimens for Pap test analysis. The InPath™ e^2 Collector™ should not be used after the first 10 weeks of gestation in pregnant patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Ingram
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013258